

In re National Prescription Opiate Litigation: MDL 2804

Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Lacey Keller is a data-mining expert. She applied certain industry standard metrics as well as defendants' own SOM compliance metrics to analyze data that was available to Manufacturers and demonstrated how using that data for SOM purposes would have identified orders of unusual size, frequency, or pattern. Her analysis shows that had Manufacturers applied data analytic techniques similar to those used by Keller, they could have identified suspicious orders in Cuyahoga and Summit responsible for millions of opioid prescriptions. They also could have identified by name numerous doctors and pharmacies in Summit and Cuyahoga connected to highly suspicious transactions.

Keller's opinions are well-supported by the evidence and will help the fact finder answer questions that lie at the core of this litigation: whether Manufacturers had tools and data at their disposal that would have been effective in identifying orders of unusual size, frequency, or pattern and what the use of those tools and data would have revealed.

Data-mining is generally accepted in the scientific community and routinely used both in the pharmaceutical industry and among regulators worldwide. Defendants do not question Keller's qualifications as a data-mining expert. Nor do not suggest that the fact-finder would be competent to perform anything like the complex "number crunching" performed by Keller.

A data-mining expert need not have experience with the precise subject matter at issue. Nor is an expert required to know answers to all the questions a case presents. Accordingly, Keller is not required to opine whether the orders flagged by her analysis were actually "suspicious" within the meaning of 21 C.F.R. § 1301.74(b).

Manufacturers object that Keller fails to include in her analysis consideration of the "due diligence" that was supposedly part of their SOM programs. Their argument is founded on a fundamental mischaracterization of the role of due diligence under the CSA. Due diligence is not a prerequisite to a determination whether an order is "suspicious"; rather, due diligence is something performed, if at all, only after a suspicious order is discovered.

It is of no moment that Keller is unable to say which, if any, of Manufacturers actually possessed the data she used. All of the Manufacturers had access to the data. The fact that many of them relied on it is sufficient to establish its reliability. To the extent Manufacturers object to Keller having used metrics other than those they prefer, their objection goes to the weight of the evidence, not its reliability.

The fact that Keller relies on hypotheticals and makes assumptions does not undermine the reliability of her opinion. Experts are permitted to testify based on hypotheticals, and Manufacturers' attack on her assumptions goes to the weight and not the admissibility of her opinion.